

Notice of Allowability

Application No.

10/784,842

Examiner

Joseph D. Anthony

Applicant(s)

GUTIERREZ ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 02/17/2006.
2. ☒ The allowed claim(s) is/are 88-94,96-106,108-119 and 121-125.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 05/02/05
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David G. Rosenbaum on 05/22/06.

The application has been amended as follows:

Claim 88 (Currently Amended) An antioxidant composition comprising: 1) a polycationic chitosan casein phosphopeptide complex and 2) at least one oil rich in Omega-3 or an oil soluble active operable to inhibit oxidation, the at least one oil is selected from the group consisting of vegetable oils[,] and animal oils; and the at least one oil soluble active is selected from the group consisting of vitamins, nutraceuticals, pharmaceuticals [or] and combinations thereof.

Claim 89 (Currently Amended) The composition of Claim 88 wherein the polycationic chitosan casein phosphopeptide is [a caseinophosphopeptide-chitosan complex] immiscible in oil.

Claim 91 (Currently Amended) The composition of Claim 88 wherein the polycationic chitosan casein phosphopeptide is a polycationic chitosan caprine casein phosphopeptide.

Claim 105 (Currently Amended) An antioxidant composition comprising: 1) a polycationic chitosan casein fragment complex immiscible in oil, wherein [the] said casein fragment is [at least one of] a phosphopeptide, [a glycopeptide, a glyceride or combinations thereof,] and 2) at least one oil or an oil soluble active operable to inhibit oxidation, wherein said at least one oil is selected from the group consisting of vegetable oils [including] comprising rice bran oil, flax[,] oil, chia[,] oil, hemp[,] oil, castor[,] oil, soybean[,] oil, lesquerella[,] oil, dehydrated castor oil, oil rich in Omega-3, or vegetable oils containing conjugated linoleic acid, and animal oils [including] comprising fish[,] oil, egg[,] oil, poultry[,] oil, and beef oils rich in Omega-3, or animal oils containing conjugated linoleic [acid, or] acid; wherein said oil-soluble actives [including] comprise vitamins, nutraceuticals, pharmaceuticals, [or] flavors, or combinations thereof.

Claim 118 (Currently Amended) An product comprising: 1) at least one polycationic chitosan casein phosphopeptide complex, wherein the polycationic chitosan casein phosphopeptide complex imparts at least one function selected from the group consisting of inhibiting oxidation of oil-in-water or water-in-oil emulsions, preventing bone mineral loss in a mammal, and preventing hypercholesterolemia in a

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mammal and 2) at least one oil or an oil soluble active operable to inhibit oxidation selected from the group consisting of vegetable oils [including] comprising rice bran oil, flax[,] oil, chia[,] oil, hemp[,] oil, castor[,] oil, soybean[,] oil, lesquerella[,] oil, dehydrated castor oil, oil rich in Omega-3, or vegetable oils containing conjugated linoleic acid, and animal oils [including] comprising fish[,] oil, egg[,] oil, poultry[,] oil, and beef oils rich in Omega-3, or animal oils containing conjugated linoleic [acid, or] acid; wherein said oil- soluble actives [including] comprise vitamins, nutraceuticals, pharmaceuticals, [or] flavors, or combinations thereof.

In the **last line** of each of dependent claims 90, 92, 94, 96, 97, 99, 102, 109, 110, 115, and 116 delete "or" and insert therefor --and--.

In claim 108, line 2, delete "107" and insert therefor --105--.

In claim 124, line 3, after the word "and" insert --vegetable oils containing--.

Claim 125 (Currently Amended) The composition of claim 88, wherein the animal oil is selected from the group consisting of fish[,] oil, egg[,] oil, poultry[,] oil, [and] beef oils rich in Omega-3 and animal oils containing conjugated linoleic acid.

Claims 95, 107 and 120 are canceled.

Reasons For Allowance

2. The following is an examiner's statement of reasons for allowance: Applicant's Amendment submitted on 02/17/06 clearly introduced NEW MATTER to all three independent claims 88, 105 and 118 in regards to the limitation of: "a polycationic casein". Contrary to applicant's argument that support for such an amendment is found in "original claims 46 and 47 submitted" is the fact that canceled claims 46 and 47 were NOT original claims at all but were first submitted as new claims in the amendment filed on 04/28/05. New claims 45-64 were subsequently withdrawn by the examiner in the office action mailed 07/18/05 as being drawn to a non-elected invention by original presentation. The only support that the examiner can find for the limitation of "polycationic" is in reference to chitosan which has a polycationic character at an acidic pH, see page 24, lines 8-11 of the specification. Because of the above fact, all independent claims were limited to --polycationic chitosan-- to be enabled.

The examiner holds that all independent claims, as amended above, are novel and unobvious over the prior-art of record since the prior-art of record neither teach nor suggest an antioxidant composition, a composition/product preventing bone mineral loss in a mammal, or a composition/product preventing hypercholesterolemia in a mammal, wherein said composition/product comprises the claimed polycationic chitosan casein phosphopeptide complex in combination with a vegetable oil or an animal oil or an oil soluble active operable to inhibit oxidation.

A special note should be made to Koide et al. U.S. Patent Number 5,290,685 which teach a method for separating phosphopeptides from an aqueous solution

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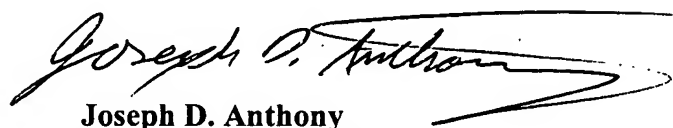
containing casein peptides, wherein said aqueous solution was prepared by treating casein with an enzyme selected from the group consisting of trypsin, pepsin, chyrotrypsin and papain, comprising: (a) adjusting the pH of the aqueous solution of casein peptides to a pH value of from 1.5 to 5.0; (b) *contacting the aqueous solution of casein peptides with a crosslinked chitosan molding and adsorbing said casein peptides onto said crosslinked chitosan molding*; (c) *desorbing phosphopeptides from said crosslinked chitosan molding under pH conditions of less than 1.5 or more than 5.0 to obtain a solution containing phosphopeptides*; and (d) concentrating the solution containing phosphopeptides obtained in step (c) to give a concentrated solution of phosphopeptides and optionally spray-drying further said concentrated solution to form powdered phosphopeptides, see abstract and claim 1. It is clear from Koide et al's method that step (b) forms an intermediate product that would seem to read on applicant's polycationic chitosan casein phosphopeptide complex. Yet it is also clear from Koide et al method that said polycationic chitosan casein phosphopeptide complex is only an intermediate product since in step (c) *desorbing phosphopeptides from said crosslinked chitosan molding under pH conditions of less than 1.5 or more than 5.0 to obtain a solution containing phosphopeptides* occurs. Furthermore, there is absolutely no teaching or suggestion in Koide et al to use the intermediate polycationic chitosan casein phosphopeptide complex product of step (b) in a composition that also comprises a vegetable oil or an animal oil or an oil soluble active operable to inhibit oxidation as claimed by applicant.

The other examiner amendments were made to overcome various 35 USC 112 second paragraph issues and to cancel redundant claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Examiner Information

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Joseph D. Anthony whose telephone number is (571) 272-1117. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Vasu Jagannathan, can be reached on (571) 272-1119. The centralized FAX machine number is (571) 273-8300. All other papers received by FAX will be treated as Official communications and cannot be immediately handled by the Examiner.



Joseph D. Anthony
Primary Patent Examiner
Art Unit 1714

5/22/06